

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

FEDERAL TRADE COMMISSION;  
STATE OF NEW YORK; STATE OF  
CALIFORNIA; STATE OF ILLINOIS;  
STATE OF NORTH CAROLINA; STATE  
OF OHIO; COMMONWEALTH OF  
PENNSYLVANIA; and  
COMMONWEALTH OF VIRGINIA,

Plaintiffs,

v.

VYERA PHARMACEUTICALS, LLC;  
PHOENIXUS AG; MARTIN SHKRELI,  
individually, as an owner and former officer  
of Vyera Pharmaceuticals, LLC and  
Phoenixus AG (formerly known as Turing  
Pharmaceuticals, LLC and Turing  
Pharmaceuticals AG); and KEVIN  
MULLEADY, individually, as an owner and  
director of Phoenixus AG and a former  
executive of Vyera Pharmaceuticals, LLC

Defendants.

Case No. 1:20-cv-00706-DLC

**DEFENDANT MARTIN SHKRELI'S  
PRETRIAL MEMORANDUM OF LAW**

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## **I. INTRODUCTION**

Plaintiffs, the Federal Trade Commission (“FTC”) and seven state Attorneys General, have had over a year of discovery in this unprecedented action, and a five-year investigation before filing the action, to develop evidence that Martin Shkreli, along with Kevin Mulleady—the only individuals ever named in a federal government action alleging monopolization under Section 2 of the Sherman Act—violated federal and state antitrust laws. The record is clear that they cannot do so. The Court must hold plaintiffs to their burden of proof and reject plaintiffs’ claims against Mr. Shkreli.

As one of the co-founders of Vyera, Mr. Shkreli believed that the company could find new cures for rare and neglected diseases while creating value for Vyera’s shareholders. With respect to Daraprim, he believed that the company could create a better version of the drug, and worked hard, along with a first-rate team of scientists that he personally recruited, to make this vision a reality. He authorized the price increase of Daraprim—a drug that had been largely ignored by the pharmaceutical community for nearly 60 years—to align the price with other similar life-saving drugs and to use the proceeds for research and development to make a better version of Daraprim. He urged Vyera to focus on research and development, because he believed that the company had an obligation to the rare disease patient community to invest any profits in new and better drugs. The law is crystal clear that raising prices is not unlawful, and in fact is an important part of our free market system. So, despite plaintiffs’ attempts to make it so, this case is not about the Daraprim price increase, but rather, whether plaintiffs can sustain their burden of proving that Mr. Shkreli violated the antitrust laws. The record shows that plaintiffs come up woefully short.

Mr. Shkreli’s work with Vyera and Daraprim was cut short when he was arrested and resigned as CEO in December 2015. During the four and a half months he was with Vyera, he was not involved in any of the distribution or supply agreements that form the basis of plaintiffs’

allegations. Indeed, the record shows that almost all of those agreements were negotiated, entered and signed after Mr. Shkreli had left Vyera. In addition, the record is devoid of any evidence that he was involved in those agreements after he left.

Nor does the record show conduct by Mr. Shkreli since he left Vyera that can sustain plaintiffs' antitrust claims. The record is now clear that plaintiffs' reliance on a false newspaper allegation that Mr. Shkreli was "running" Vyera from prison (*see* Am. Compl. (ECF 87) ¶ 45), was misplaced. No such evidence has been presented. At most, the evidence shows that from the time he left Vyera to the current day, Mr. Shkreli has made suggestions to Vyera management—as any large shareholder would be expected to—regarding the business, most of which management ignored. And Mr. Shkreli did not have the authority to, and did not, direct any of Vyera's corporate actions once he left the company, including any actions relating to Daraprim.

Plaintiffs bring no claims against Mr. Shkreli in his individual capacity; their theory of liability is a derivative one, *i.e.*, that as a former corporate officer and director, and current shareholder, Mr. Shkreli is liable for corporate conduct in which he allegedly "participated." But putting aside whether this is the proper standard for the Court to apply, the record supports neither anticompetitive conduct by Vyera nor Mr. Shkreli's participation in such conduct. For all the reasons set forth in Defendants' Pre-Trial Memorandum, there is no basis for the Court to find that Vyera violated the law. The case against Mr. Shkreli should end right there. But even assuming the Court were to find Vyera liable, which it should not, there is no basis for the Court to find liability against Mr. Shkreli, for several reasons.

First, there is no evidence that Mr. Shkreli, as an individual, possesses monopoly power, a necessary element of a Section 2 claim, and plaintiffs cannot point to a single case that holds that an individual acting on behalf of a corporation assumes the monopoly power of the company. In

fact, as plaintiffs' own expert Scott Hemphill testified, the concept does not make any sense. So the Section 2 claims against Mr. Shkreli cannot survive even if the Court were to find Vyera liable under Section 2.

Second, there is no basis for holding Mr. Shkreli liable under Section 1. Mr. Shkreli had no involvement in any of the allegedly anticompetitive agreements Vyera entered into, most of which were entered after he had left the companies. Nor can Mr. Shkreli be held liable through his status as a former officer and director, or current minority shareholder. Corporate officers and directors can be held liable only for conduct by the company that constitutes a *per se* antitrust violation, which is not alleged here, and despite being a large shareholder, Mr. Shkreli does not have the authority to control Vyera's decisions. Plaintiffs' allegation that Mr. Shkreli's exercising his rights as a large shareholder was somehow improper goes nowhere, because there is no evidence that Mr. Shkreli ever influenced any decisions of the Phoenixus board relating to Daraprim.

Finally, because the state law claims against Mr. Shkreli filed by the state Attorneys General generally mirror the federal claims, they all fail for the same reasons.

Even if plaintiffs were able to present sufficient evidence that Mr. Shkreli violated the law, which they cannot, the record is also devoid of any evidence that Mr. Shkreli was unjustly enriched by the alleged scheme. Thus, plaintiffs' unprecedented request for unspecified monetary relief and an injunction that would ban Mr. Shkreli from all aspects of the pharmaceutical industry for life is wholly without foundation.

Because he believed so deeply in Vyera's mission, Mr. Shkreli invested \$18 million of his own money into the company and received no salary or compensation of any kind. Indeed, far



from being “unjustly enriched,” Mr. Shkreli has made *no profit* from Daraprim or any other drug that Vyera has sold. So plaintiffs are not entitled to any monetary relief against Mr. Shkreli.

And plaintiffs’ request for a lifetime industry ban is simply an overreach by the plaintiffs.

First, there is no factual foundation on which the Court could base a permanent injunction, because the record shows that as of the time the Complaint was filed, Mr. Shkreli was not “violating” or “about to violate” the law. The Amended Complaint makes reference to communications Mr. Shkreli had—months before the Complaint was filed—with Vyera executives about the company, and contains a vague allegation that Mr. Shkreli was at that time “looking for” drugs other than Daraprim to hatch a similar scheme (Am. Compl. (ECF 87) ¶ 293), but no such evidence was developed in discovery. Thus there is no evidentiary support for any type of injunction.

Second, even if there were support in the record for an injunction, a lifetime ban from the industry would be well beyond the bounds of any reasonable sanction for the Court to impose. Any sanction must be narrowly tailored to the proof in the case. Even assuming plaintiffs proved every single allegation against Mr. Shkreli, which they cannot, a lifetime ban from the pharmaceutical industry would amount to unnecessary and unreasonable punishment, which is not the proper function of a court in equity and, in any event, inappropriate in a rule of reason antitrust case.

For all these reasons, the Court should reject all the claims against Mr. Shkreli.<sup>1</sup>

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<sup>1</sup> Mr. Shkreli incorporates by reference in their entirety Defendants’ Memorandum Addressing Questions of Law Expected To Arise at Trial (“Defendants’ Pre-Trial Memorandum”) and Defendant Kevin Mulleady’s Pre-Trial Memorandum of Law (“Mulleady’s Pre-Trial Memorandum”).

## II. FACTS

### A. **Founding of Vyera and Phoenixus<sup>2</sup>**

Martin Shkeli has always had a passion for finding cures for rare diseases, and spent years after college studying drug trials, chemistry, and biopharmaceutical stocks. Written Direct Testimony of Martin Shkreli (“Shkreli Decl.”) ¶ 9. In September 2014, after several years at Retrophin, a company he founded in 2010 that focused on rare diseases such as Duchenne Muscular Dystrophy (DMD) and pantothenate kinase-associated neurodegeneration (PKAN), Mr. Shkreli co-founded Vyera and Phoenixus. *Id.* ¶ 10-16. He personally invested approximately \$18 million into Vyera. *Id.* ¶ 15. From the date of Vyera’s and Phoenixus’ founding until December of 2015, Mr. Shkreli was the CEO of Vyera and a Director and Chairman of the Board of Directors of Phoenixus. *Id.* ¶ 17. He never received a salary or any form of compensation from either company. *Id.*; Tilles Dep. Tr., at 194:25-195:9.

Early on, Mr. Shkreli advised the Phoenixus Board of Directors that while he had been acting as Vyera’s CEO, it was not a role that he planned or wanted to fill much longer, and urged the company to identify and hire a new CEO with greater pharmaceutical industry experience than he had. Shkreli Decl. ¶ 18. Mr. Shkreli recruited well-credentialed and experienced scientists at Vyera to conduct research and development (“R&D”), including Vyera’s head of R&D, Eliseo Salinas, M.D, former head of global R&D for Shire Pharmaceuticals; Dr. Adam Brockman, a parasitologist with two decades of experience in the biopharmaceutical industry; Dr. Matthew Welsch, a medicinal chemist; Dr. Steven Thomas, also a medicinal chemist and currently Chief Scientific Officer for ValenzaBio; and Dr. Wendy Cousin, currently the lead scientist at Spring

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<sup>2</sup> Turing Pharmaceuticals LLC and Vyera Pharmaceuticals LLC will be referred to in this brief as “Vyera.” Turing Pharmaceuticals AG and Phoenixus AG will be referred to as “Phoenixus.”

Discovery. *Id.* ¶ 19. Mr. Shkreli and his co-founders envisioned that Vyera would, among other things, acquire established pharmaceuticals that treated rare diseases but were largely ignored by the larger pharmaceutical companies. *Id.* ¶ 22. One of these drugs was Daraprim, which Vyera acquired from Core Pharma in August of 2015. *Id.* ¶ 32. Mr. Shkreli believed that Vyera could develop a better version of Daraprim with less severe side effects, while at the same time providing shareholder value. *Id.* ¶ 34.

#### **B. The Price Increase and R&D**

After Vyera purchased Daraprim, it increased its price from \$17.50 to \$750 per pill. Mr. Shkreli authorized the price increase because he believed that Daraprim was significantly underpriced relative to other lifesaving medications such as drugs that treat hepatitis C (*e.g.*, Sovaldi and Harvoni), and HIV drugs. Shkreli Decl. ¶ 33. At \$750 per pill, Daraprim compared very favorably to hepatitis C and HIV drugs when one considers the cost of a course of treatment. *Id.* For example, a full course of treatment for hepatitis C costs approximately \$80,000, whereas, at \$750 per pill, a full course of treatment for toxoplasmosis costs approximately \$40,000. *Id.* And of those three diseases—hepatitis C, HIV, and toxoplasmosis—only one, toxoplasmosis, is rapidly fatal. *Id.*

Mr. Shkreli also believed that the price increase would allow Vyera to invest in R&D to create a new and better version of Daraprim. *Id.* ¶ 34. On its own, Daraprim is highly toxic and must be taken in combination with another drug called leucovorin. *Id.* Adding a second drug to the treatment regimen can result in reduced adherence to the regimen. *Id.* Mr. Shkreli's vision was to make a combination pill containing both Daraprim and leucovorin. *Id.* Mr. Shkreli believed that if Vyera were going to increase the price of the drug, it had an obligation to the patient community to invest the revenues from the price increase into research and development. *Id.* ¶

35. For this reason, he never took a salary or received any compensation from Vyera or Phoenixus. *Id.* ¶ 17.

Mr. Shkreli urged the company to invest revenues from the price increase into new drug development, including either a drug with an entirely new chemical composition, effective against toxoplasmosis, or a combination pill combining Daraprim and leucovorin. *Id.* ¶ 36. Led by a team of four to five doctors in the R&D department, Vyera focused its research and development efforts on making a better form of Daraprim. *Id.* Vyera was the first company to develop new toxoplasmosis drugs, including a new drug (TUR-006) that would obviate the need for sulfa drugs and thus remove the allergic complications that most HIV patients experience. *Id.* Vyera also had two papers published in the Journal of Medicinal Chemistry about these innovations. *See* Hopper, Allen T., et al., *Discovery of Selective Toxoplasma gondii Dihydrofolate Reductase Inhibitors for the Treatment of Toxoplasmosis*, J. Med. Chem. 2019, 62, 1562-1576; Janetka, James W., et al., *Optimizing pyrazolopyrimidine inhibitors of calcium dependent protein kinase 1 for treatment of acute and chronic toxoplasmosis*, J. Med. Chem. 2020 June 11, 63(11), 6144-6163. In addition, while Mr. Shkreli was at Vyera, the company developed the first ever toxoplasmosis-specific inhibitor of the enzyme DHFR, which reached Phase 1 clinical development, a stage that few research projects attain. *Id.* ¶ 37.

Daraprim was just one of over a dozen drugs that Vyera acquired or developed. *Id.* ¶ 39. These include: leronlimab, an antibody used to treat HIV (licensed from CytoDyn Inc.); intranasal Ketamine, which treats acute suicidality; Stiripentol, used for Dravet Syndrome, a severe encephalopathy affecting children; oxytocin, which treats autism; Vecamyl, used for malignant hypertension and spinal cord injury; two new toxoplasmosis drugs; four new medicines and new nucleic acid therapies for various rare diseases; and new, cheaper generic drugs. *Id.*

### C. Vyera's Sourcing of API

After he left the company, Mr. Shkreli learned that Vyera signed a supply contract with a Japanese company called Fukuzyu. Shkreli Decl. ¶ 43. Mr. Shkreli did not negotiate or sign, and is not familiar with any of the terms of, Vyera's contract with Fukuzyu. *Id.* As a matter of good business practice, it is important for a pharmaceutical company to have a secondary or back-up API supplier available to meet its needs if its primary supplier becomes unable to do so. *Id.* ¶ 45; Pellicione Written Testimony at ¶ 26; Written Direct Testimony of Kevin Mulleady ( "Mulleady Decl.") ¶ 42. For Vyera, which depended on Daraprim sales to generate revenue, having a back-up supplier was important to ensure both that it could continue to offer and make sales of Daraprim and that there would be no interruption in the supply of Daraprim to the patients who depend upon it. Shkreli Decl. ¶ 46; Salinas Dep. Tr. at 158:23-160:5. For these reasons, while Mr. Shkreli served as CEO of Vyera, he asked the manufacturing team to look into contracting with not only a primary supplier, but also a secondary supplier. *Id.* ¶ 47. That process was not completed by the time he left the company in December 2015. *Id.* ¶ 48. Prior to that time, Vyera had had discussions with an Indian company, Neuland Laboratories, about supplying Vyera with pyrimethamine. *Id.* However, those discussions did not progress very far. *Id.* In addition, Vyera's head of manufacturing, Dr. Hasmukh Patel, approached a second company, Ipca Laboratories, about supplying API in the United States, during the time that Mr. Shkreli was CEO. *Id.* However, those efforts were ultimately unsuccessful, as Dr. Patel left the company in November or December of 2015. *Id.*

Two years later, in 2017, when Mr. Shkreli was no longer an employee of Vyera or director of Phoenixus, he became aware of another potential API manufacturer of pyrimethamine, an Indian company named [REDACTED]. *Id.* ¶ 49. A representative of [REDACTED] approached a former Vyera employee, Edwin Urrutia, and informed him that [REDACTED] was working towards manufacturing

pyrimethamine. *Id.* ¶ 50. That information was passed on to Mr. Shkreli through his attorney. *Id.* Around that same time, Mr. Shkreli fortuitously learned in conversations with either Mr. Mulleady or Vyera employee Akeel Mithani that Vyera was already engaged in discussions with [REDACTED]. *Id.* ¶ 51. Mr. Shkreli informed Mr. Mulleady of what he had learned from Mr. Urruita, namely that [REDACTED] was working towards the manufacture of pyrimethamine. *Id.* ¶ 52. Mr. Shkreli did not know whether Mr. Mulleady and Mr. Mithani already knew that [REDACTED] was working towards the manufacture of pyrimethamine, but thought it was important to inform Vyera management of this fact because he thought that it could mean that entry of a generic alternative to Daraprim was imminent, which would have a significant effect on his investment in the company *Id.* ¶ 53-54.

As a shareholder, Mr. Shkreli felt that his role was limited to conveying the information to management so that they could project when that entry might occur and make whatever decisions they thought appropriate to prepare for it—such as reducing the sales force—but that any decision about what to do with the information was for Vyera management to make. *Id.* ¶ 54. Mr. Shkreli also recognized that [REDACTED] represented a potential secondary or back-up source of pyrimethamine for Vyera, and that [REDACTED] could be a potential partner with Vyera in creating a combined drug containing pyrimethamine and leucovorin. *Id.* ¶ 55. Mr. Shkreli does not know what, if anything, Mr. Mulleady did with the information he provided him about [REDACTED]. *Id.* ¶ 56. Mr. Shkreli later learned that Vyera approached [REDACTED] about purchasing pyrimethamine, and he counseled Mr. Mithani, who was inexperienced in such matters, on how to approach [REDACTED] on this subject and the possible partnership for a combination pill. *Id.* Mr. Shkreli also learned that Vyera entered into an API supply agreement with [REDACTED]. *Id.* ¶ 57. However, Mr. Shkreli did not negotiate that agreement, did not sign it, and has never seen it. *Id.*

#### **D. Vyera's Distribution of Daraprim**

Mr. Shkreli has very little knowledge concerning the specifics of Vyera's distribution of Daraprim, other than the fact that it is offered through specialty distribution, just as it was under its previous owner, CorePharma. Shkreli Decl. ¶ 58. The distribution of Daraprim was handled by Vyera executives who understood specialty distribution, and not Mr. Shkreli. *Id.* ¶ 59. Mr. Shkreli did not negotiate, did not sign, and is not familiar with any of the terms of any of the distribution contracts that Vyera entered with distributors. *Id.* ¶ 60.

#### **E. The Proxy Fight**

In 2016, Mr. Shkreli was not satisfied that Vyera was moving in the right direction, and became concerned about the future of the company, which at that time was his largest investment. Shkreli Decl. ¶ 61. He was particularly frustrated by the way that Ron Tilles, who had been named interim CEO, was managing Vyera. *Id.* As a result, Mr. Shkreli organized a proxy fight to remove members of the Board of Directors of Phoenixus that he did not think were doing a good job, including Mr. Tilles. *Id.* The proxy fight was successful, and Mr. Shkreli's slate of directors, which included Kevin Mulleady and Akeel Mithani, was elected. *Id.*

The proxy fight was totally unrelated to Vyera's sale and distribution of Daraprim. *Id.* ¶ 62. Despite the fact that Mr. Shkreli's share ownership in Phoenixus allowed him to make changes to the Board of Phoenixus, he never used that power to affect in any way Vyera's distribution of Daraprim, its acquisition of pyrimethamine API for Daraprim, or its policies and practices related to reporting of data. *Id.* ¶ 63.

#### **F. Generic Competition**

As a shareholder of Phoenixus, Mr. Shkreli from time to time makes suggestions to Vyera management regarding the company. Shkreli Decl. ¶ 64. Often these suggestions are ignored. *Id.*; Mulleady Decl. ¶ 64; Mulleady Dep. Tr., at 122:14-123:10; Mithani Dep. Tr., at 259:10-18.

One significant example of Vyera management ignoring Mr. Shkreli's suggestions after he left the companies is their failure to follow his suggestion that Vyera develop an alternative to or a better form of Daraprim to treat toxoplasmosis. Shkreli Decl. ¶ 64.

Ever since Vyera purchased Daraprim, Mr. Shkreli has anticipated the development of a generic competitor. *Id.* ¶ 66. Mr. Shkreli's view, as he expressed to his Vyera colleagues, is that the only way to mitigate the impact of generic competition is to develop a new or better drug. *Id.* In a September 26, 2015 email to Vyera employee Ed Painter, who had asked Mr. Shkreli if an annual price reduction commitment might discourage generics from entering the market, Mr. Shkreli told Mr. Painter that he did not think there is much that can be done to prevent generics from entering the market other than to introduce a new drug. *Id.* ¶ 67; Trial Ex. DX 126. As a result, when he was CEO of Vyera, Mr. Shkreli made sure that R&D was a core focus for the company. Shkreli Decl. ¶ 68. And Vyera employees spent a lot of time thinking about how to make a better version of Daraprim. *Id.*

Mr. Shkreli explained his philosophy about R&D in a 2017 email to Tracy Seckler, the Chief Visionary Officer for Charley's Fund, a charity dedicated to developing life-saving treatments for DMD. *Id.* ¶ 69. Mr. Shkreli told Ms. Seckler that if a company increases the price of a pharmaceutical, as Vyera did, it needs to use the profits to fund lab research and develop a better drug. *Id.*; Trial Exhibit DX 481. After his resignation, Mr. Shkreli repeatedly advised and implored Vyera employees to continue this research. Shkreli Decl. ¶ 70. But for several years after he left the company, the management had very little interest in R&D. *Id.* As a result, Vyera has not developed a new or better drug to treat toxoplasmosis. *Id.* Mr. Shkreli is not aware of any plan by Vyera—which owned Daraprim for only four months before he resigned as CEO—to stop



or slow a generic pharmaceutical company from manufacturing and selling a generic version of Daraprim, which he does not believe is possible. *Id.* ¶ 71.

**G. Mr. Shkreli's Involvement in Vyera After February 2016**

Mr. Shkreli resigned as Vyera's CEO on December 18, 2015, and subsequently resigned from Vyera's Board on February 10, 2016. Shkreli Decl. ¶ 73. Since his departure, Mr. Shkreli's only role in Vyera has been as a shareholder. *See* Tilles Dep. Tr., at 147:23-148:2, 183:3-24; Retzlaff Dep. Tr., at 210:3-10; Shkreli Decl. ¶ 73. As a shareholder, Mr. Shkreli is entitled to vote his shares in Phoenixus and to contact company management about sales data like any other Vyera shareholder. Tilles Dep. Tr., at 183:17-22; Retzlaff Dep. Tr., at 181:9-10; Shkreli Decl. ¶ 75. But, Mr. Shkreli has not had any role in managing nor the authority to manage Vyera since his departure—and the company's actions make this clear. After resigning from Vyera, Mr. Shkreli was not able to control or manage the business of Vyera, and was not able to control the decision-making of Vyera as it related to Daraprim. Costopoulos Dep. Tr., 141:20-142:20. More specifically, Mr. Shkreli did not negotiate any supply agreements on behalf of Vyera during this time period (or any other time period), nor was Mr. Shkreli able to control the decision-making as it related to Vyera's distribution agreements for Daraprim. Costopoulos Dep. Tr., 144:2-145:4.

After Mr. Shkreli left Vyera as CEO in December of 2015, it was the company's view that Mr. Shkreli should have no role in the management of the company. Costopoulos Dep. Tr., 145:18-146:9. Mr. Shkreli has not attended meetings of Vyera's Senior Leadership team since December 2015 and, as an example, was specifically barred from attending such meetings as early as February 2016 "because he was no longer a part of management" of Vyera. Costopoulos Dep. Tr., at 55:23-57:18, 141:20-142:12; Tilles Dep. Tr., at 161:25-162:22, 163:17-164:3; Retzlaff Dep. Tr., at 210:3-10. Mr. Shkreli sought a consulting agreement with Vyera after his departure, but the company refused to retain him as a consultant. Tilles Dep. Tr., at 165:4-6; Costopoulos Dep.

Tr., at 145:12-17; Shkreli Decl. ¶ 78. And, while Mr. Shkreli has made suggestions to company management, these suggestions have often been ignored. Tilles Dep. Tr., at 10-13; Shkreli Decl. ¶¶ 64, 81. For example, when Mr. Shkreli requested a Vyera email address, company management told him that he could not have an email because he was “no longer part of the company . . . you’re not part of this.” Tilles Dep. Tr., at 84:10-13; *see also* Tilles Dep. Tr., at 189:10-18. Mr. Shkreli’s communications with Vyera management since leaving the company have focused on sales data relevant to his status as a large shareholder, consistent with the company’s view that “he’s entitled to shareholder updates, but nothing beyond that.” Tilles Dep. Tr., at 183:9-24; *see id.*, at 165:24-166:17; Retzlaff Dep. Tr., at 181:9-10; Shkreli Decl. ¶ 75. Finally, Mr. Shkreli has not been physically present at Vyera’s offices since his departure. Tilles Dep. Tr., at 173:14-174:2; Retzlaff Dep. Tr., at 211:8-11.

In sum, Mr. Shkreli’s interactions with Vyera since his departure make it clear that Mr. Shkreli has had no subsequent role in the company’s management. *See* Tilles Dep. Tr., at 184:17-22; Retzlaff Dep. Tr., at 210:3-10; Costopoulos Dep. Tr., at 141:20-142:12, 146:4-9. Since leaving the companies, Mr. Shkreli has not had the authority to make, and has not made, any decisions for Vyera or Phoenixus in any way relating to Daraprim or any other drug. Shkreli Decl. ¶ 76.

Since leaving Vyera and Phoenixus in February 2016, Mr. Shkreli has been in contact with Mr. Mulleady and current employee Akeel Mithani and, more recently, with Vyera’s current CEO and General Counsel, Averill Powers. *Id.* ¶ 80. Mr. Shkreli has known Mr. Mulleady and Mr. Mithani for years and has considered both of them friends. *Id.* Following his resignation from Vyera, he has had many discussions and communications with both of them on various topics ranging from pop culture to personal matters to matters affecting Vyera. *Id.* ¶ 81. From the time that Mr. Powers was promoted to interim CEO in December 2018, Mr. Shkreli has had a limited

number of conversations with him, beginning in 2020. *Id.* In the course of the many discussions Mr. Shkreli has had with Messrs. Mulleady, Mithani and Powers, he has made suggestions to each of them about Vyera, primarily relating to business development, in his role as a major shareholder in Phoenixus. *Id.* ¶ 81. But no Vyera employee, including Mr. Mulleady, Mr. Mithani, or Mr. Powers, is required or bound to follow Mr. Shkreli's suggestions. *Id.* In fact, more often than not they ignore, or at least do not follow, those suggestions, which has been a continuing source of frustration for Mr. Shkreli. *Id.*; Mulleady Dep. Tr., at 122:14-123:10; Mithani Dep. Tr., at 259:10-18.

### **III. ARGUMENT**

#### **A. Plaintiffs Have Failed to Meet Their Burden of Proving that Mr. Shkreli Violated the Sherman Act or Analogous State Statutes**

Plaintiff have failed to meet their burden of proving that Mr. Shkreli violated either Section 1 or Section 2 of the Sherman Act, or state-level analogous statutes.

##### **1. There Can Be No Section 2 Liability Against Mr. Shkreli**

The elements of a claim under Section 2 of the Sherman Act are (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historical accident. *Gust, Inc. v. AlphaCap Ventures, LLC*, 15cv6192, 2016 WL 4098544, at \*4 (S.D.N.Y. July 28, 2016) (Cote, J.) (quoting *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 133 (2d Cir. 2014)).

To succeed on a Section 2 claim, a plaintiff must prove that a defendant possesses monopoly power (a/k/a market power) in a relevant market. *Discover Fin. Servs. v. Visa U.S.A. Inc.*, 598 F. Supp. 2d 394, 404 (S.D.N.Y. 2008) (Jones, J.) (explaining that an element of a Section 2 claim is “the possession of monopoly power in the relevant market” (quoting *United States v.*

*Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)); *RxUSA Wholesale, Inc. v. Alcon Labs., Inc.*, 661 F. Supp. 2d 218, 239 (E.D.N.Y. 2009) (same).

Plaintiffs' Section 2 claims against Mr. Shkreli fail because Mr. Shkreli does not possess monopoly power.<sup>3</sup> To meet the monopoly power element, a plaintiff must show that the defendant possesses "the power to control prices or exclude competition." *Discover Fin. Servs.*, 598 F. Supp. 2d at 404 (quoting *Heerwagen v. Clear Channel Communications*, 435 F.3d 219, 226 (2d Cir. 2006)). That analysis fails when applied to individuals. Plaintiffs' own expert, Scott Hemphill, Ph.D., J.D., will offer no opinion that Mr. Shkreli possesses monopoly or market power. In fact, Dr. Hemphill was flummoxed by the mere suggestion that Mr. Shkreli, or Mr. Mulleady, could possibly possess market power. When asked, at his deposition, if he intended to testify whether "either of the individual defendants, meaning Mr. Shkreli or Mr. Mulleady, possessed market power," Dr. Hemphill responded, "I don't know what that would mean. Market power and monopoly power would be evaluated by reference to the sellers of products." Hemphill Dep. Tr., at 245:10-20. Thus, because Mr. Shkreli and Mr. Mulleady are not "sellers of products," the only basis for liability Dr. Hemphill could articulate against them, at his deposition, is that "they are the same thing as Vyera for purposes of an economist." *Id.* at 245:10-23. But under the law, that is not so.

Courts that have addressed the rare monopolization claims brought against individuals have held that an individual cannot be liable on a monopolization theory unless the individual possesses monopoly power. In *Winn-Dixie Stores, Inc. v. E. Mushroom Mktg. Coop.*, No. 15-6480, 2019

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<sup>3</sup> The Court previously struck Mr. Shkreli's Fifteenth Affirmative Defense on this ground, holding that "to succeed at trial, the plaintiffs need not prove that Shkreli . . . personally possessed any market power." Oct. 6, 2020 Opinion and Order (ECF 365), at 10. However, that affirmative defense merely restates what is, in the first instance, plaintiffs' burden to prove. Thus, Mr. Shkreli respectfully reasserts that the government must, but cannot, meet this burden.

WL 130535 (E.D. Pa. Jan. 8, 2019), the plaintiffs sued a cooperative, its members (including natural born individuals), and certain third-party distributors, alleging claims under, *inter alia*, Section 2 of the Sherman Act, alleging that the defendants violated Section 2 by “conspiring to acquire or maintain, acquiring or maintaining, and/or attempting to acquire or maintain monopoly power.” *Id.* at \*5. However, the claims against the individuals could not stand because “to sustain their claims of monopolization and attempted monopolization,” the court held, plaintiffs must “prove the required elements against *each individual defendant*.” *Id.* (quotations and citation omitted, emphasis added). The plaintiffs’ claims against the individual defendants failed because just as in a related class action in which the plaintiffs failed to allege that “any of the individual member defendants had a dangerous probability of achieving monopoly power” themselves, the plaintiffs in *Winn-Dixie* alleged no facts that the individual defendants possessed monopoly power themselves. *Id.*

Other courts are in accord: individuals do not possess monopoly power by virtue of their association with corporate defendants. *See Carpet Grp. Int’l v. Oriental Rug Imps. Ass’n*, 256 F. Supp. 2d 249, 284-85 (D.N.J. 2003) (granting summary judgment on Section 2 claim because plaintiffs failed to prove individual defendants possessed monopoly power, holding that plaintiffs do not even “contend that [the individual defendant,] separate from [the company,] possesses market power” and finding that “[the individual defendant] is not in the business of importing oriental rugs and therefore has no market share whatsoever ... [the defendant] as an individual possesses no power to prevent newcomers from entering the market”); *Appraisers Coal. v. Appraisal Inst.*, 845 F. Supp. 592, 602-03 (N.D. Ill. 1994) (dismissing Section 2 claim against individuals where the plaintiff made “no allegation with respect to the market power of any individual”); *see also ES Dev., Inc. v. RWM Enterprises, Inc.*, 939 F.2d 547, 554 (8th Cir. 1991)

(holding in a Section 1 case that “the Sherman Act does not impart liability for actions by an individual, regardless of their anticompetitive motive or effect, unless the individual entity possesses monopoly power.”).

Accordingly, because there is no evidence, and no expert will opine, that Mr. Shkreli possesses market power, Plaintiff’s Section 2 claims—and all related state law claims—against him fail.

## **2. There Can Be No Section 1 Liability Against Mr. Shkreli**

Section 1 of the Sherman Act proscribes every “contract, combination . . . or conspiracy, in restraint of trade or commerce.” 15 U.S.C. § 1. To satisfy the elements of a Section 1 claim, Plaintiffs must prove “(1) a contract, conspiracy, or combination, (2) which restrains trade such that the anticompetitive effects outweigh the procompetitive effects, and (3) which proximately causes injury to plaintiff.” *Naso v. Park*, 850 F. Supp. 264, 272 n.6 (S.D.N.Y. 1994) (Conner, J.) (citing *Volvo N. Am. Corp. v. Men’s Int’l Pro. Tennis Council*, 687 F. Supp. 800, 806-07 (S.D.N.Y. 1988)); see also *In re Med. X-Ray Film Antitrust Litig.*, 946 F. Supp. 209, 215 (E.D.N.Y. 1996) (Section 1 claim requires “(1) concerted action, (2) by two or more persons, (3) which unreasonably restrains interstate or foreign trade or commerce.”). Plaintiffs allege that Vyera’s distribution and supply agreements are unreasonable restraints of trade in violation of Section 1, and that Mr. Shkreli is vicariously liable because he was formerly a corporate officer and director, and is currently a shareholder. Am. Compl. (ECF 87) ¶¶ 319-22. But the evidence fails to support these claims.

First, plaintiffs cannot show a Section 1 violation by Vyera, for all the reasons articulated in Defendants’ Pre-Trial Memorandum. Because there is no liability for Vyera, there can be no liability for Mr. Shkreli. But even if the Court disagrees and finds Vyera liable under Section 1, the record does not support liability for Mr. Shkreli under Section 1.

The record does not support a finding of liability based upon Mr. Shkreli's alleged participation in the contracts. During the four and a half months he was with Vyera, he was not involved in any of the supply or distribution agreements that are the basis of plaintiffs' allegations. And the record shows that almost all of those agreements were negotiated, entered and signed after Mr. Shkreli left Vyera. Additionally, the record is devoid of any evidence that he was involved in those agreements after he had left. Mr. Shkreli has very little knowledge concerning the specifics of Vyera's distribution of Daraprim, other than the fact that it is offered through specialty distribution, just as it was under its previous owner, Core Pharma. Shkreli Decl. ¶ 58. Mr. Shkreli did not negotiate, did not sign, and is not familiar with any of the terms of any of the distribution contracts that Vyera entered with distributors. *Id.* ¶ 60.

While CEO of Vyera, Mr. Shkreli asked Vyera's manufacturing team to investigate contracting with a primary and secondary supplier of pyrimethamine. *Id.* ¶ 47. Mr. Shkreli viewed it as important for Vyera to have a secondary supplier to ensure continuity of supply. *Id.* ¶¶ 45-46. During his tenure, Vyera engaged in discussions with two companies, Neuland Laboratories and Ipca Laboratories. *Id.* ¶ 48. However, discussions with these companies did not ultimately lead to an API supply agreement and concluded in late 2015 after Vyera's head of manufacturing, Dr. Hasmukh Patel, left the company in November or December of that year. *Id.* Not long after, Mr. Shkreli resigned from Vyera and the Phoenixus Board. And, while Mr. Shkreli became aware, after he left the company, that Vyera had signed an API supply agreement with Fukuzyu, he did not negotiate that agreement, did not sign it, and is not familiar with any of its terms. *Id.* ¶ 43. Vyera's agreement with ██████ was entered into during the term of Mr. Shkreli's incarceration. Mr. Shkreli did not negotiate that agreement, did not sign it, and has never seen it. *Id.* ¶ 57.

Moreover, the record contains no evidence that Mr. Shkreli had any contact at all with anyone at any of the counterparties to the allegedly illegal agreements. Thus, there can be no “unity of purpose or a common design and understanding, or a meeting of minds in an unlawful arrangement” between Mr. Shkreli and any other person or entity, to support a Section 1 claim. *In re Elec. Books Antitrust Litig.*, 859 F. Supp. 2d 671, 681 (S.D.N.Y. May 15, 2012) (Cote, J.) (internal quotation marks omitted); *see also Mylan Pharm. v. Celgene Corp.*, CV 14-2094 ES, 2014 WL 12810322, at \*8 (D.N.J. Dec. 23, 2014).

In short, Plaintiffs have failed to carry their burden of proving that Mr. Shkreli participated in the challenged agreements such that he can be held liable for them. Therefore, plaintiffs have failed to prove their Section 1 claim—and all related state law claims—against Mr. Shkreli.

### **3. Mr. Shkreli Cannot Be Derivatively Liable for Vyera’s Conduct**

Plaintiffs’ theory of Mr. Shkreli’s liability—*i.e.*, that under agency principles Mr. Shkreli can be held liable for Vyera’s alleged anticompetitive conduct, is untenable.<sup>4</sup>

First, a director or officer cannot be liable for a company’s allegedly anticompetitive conduct unless that conduct constitutes a *per se* violation of the antitrust laws. *Murphy Tugboat Co. v. Shipowners Merchs. Towboat Co.*, 467 F. Supp. 841, 853-54 (N.D. Cal. 1979) (CEO’s knowing approval or ratification of company’s policy of refusing to deal with competitors did not impose liability under Sherman Act on CEO because the company’s policy was not a *per se* violation or “inherently wrongful.”) Here, Plaintiffs are not alleging “inherently wrongful”

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<sup>4</sup> Mr. Shkreli acknowledges that in its Opinion and Order denying Mr. Shkreli’s Motion to Dismiss (“Motion to Dismiss Order”) (ECF 365), the Court rejected Mr. Shkreli’s argument that plaintiffs’ “reverse agency” theory was the wrong standard, and ruled that it is enough that plaintiffs establish Mr. Shkreli’s “participation” in Vyera’s allegedly anticompetitive conduct. Mr. Shkreli urges the Court to reconsider this conclusion on the proper standard to apply. Nonetheless, as developed more fully herein, even under a “participation” standard Mr. Shkreli should not be held liable.



conduct or *per se* antitrust violations by Vyera, so Mr. Shkreli cannot be held liable based upon his former roles as an officer and director of Vyera.<sup>5</sup>

Second, Mr. Shkreli's status as a shareholder in Phoenixus does not confer liability. *See Harlem River Consumers Coop., Inc. v. Associated Grocers of Harlem, Inc.*, 408 F. Supp. 1251, 1270 (S.D.N.Y. 1976) (Pierce, J.) (holding that the fact that a person is a shareholder "does not give him authority to act for the corporation"). There is no evidence that Mr. Shkreli's share ownership in Phoenixus (less than 50% of Phoenixus' stock, Shkreli Decl. ¶ 75), gave him the authority to control Vyera's decisions relating to Daraprim, so as to give rise to his liability for the company's acts. *See FTC v. Med. Billers Network, Inc.*, 543 F. Supp. 2d 283, 321 (S.D.N.Y. 2008) (Holwell, J.); *FTC v. Crescent Publ'g Group, Inc.*, 129 F. Supp. 2d 311, 324 (S.D.N.Y. 2001) (Kaplan, J.). In fact, the record shows the opposite: Mr. Shkreli did *not* control Vyera's decision-making with regard to Daraprim after he left the company, and while he often made suggestions to management, more often than not those suggestions were either ignored or not followed. Mulleady Dep. Tr., at 122:14-123:10; Mulleady Decl. ¶ 64; Mithani Dep. Tr., at 259:10-18; Tilles Dep. Tr., at 10-13; Shkreli Decl. ¶¶ 64, 81. Thus, since leaving Vyera and Phoenixus, Mr. Shkreli has not had the authority to make, and has not made, any decisions for Vyera or Phoenixus in any way relating to Daraprim. Shkreli Decl. ¶ 76.<sup>6</sup>

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<sup>5</sup> Nor can Mr. Shkreli be held liable for Vyera's acts by virtue of his status as the company's former agent. "It is a basic principle of agency law that '[o]nly an agent's own tortious conduct subjects the agent to liability . . . . An agent is not subject to liability for torts committed by the agent's principal that do not implicate the agent's own conduct; there is no principle of respondeat inferior.'" *Pascarella v. Sandals Resort Int'l, Ltd.*, No. 19-cv-2543, 2020 WL 1048943, at \*6 (S.D.N.Y. Mar. 4, 2020) (Torres, J.) (alterations in original) (citation and internal quotation marks omitted).

<sup>6</sup> In addition, while Mr. Shkreli sometimes voiced his opinion as a major shareholder, the company was under no obligation to follow his advice. Shkreli Decl. ¶¶ 75, 78-81. In fact, after his resignation from Vyera and the Phoenixus Board of Directors, the companies shut him out of meetings. *Id.* ¶¶ 77-78; *see also* Costopoulos Dep. Tr., at 55:23-57:18, 141:20-142:12; Tilles Dep. Tr., at 161:25-162:22, 163:17-164:3; Retzlaff Dep. Tr., at 210:3-10.

Plaintiffs spent a lot of time in discovery focused on Mr. Shkreli's exercise of his share ownership in Phoenixus to suggest that he controlled the company, and thus, presumably, its decisions relating to Daraprim. They focused particular attention on a proxy fight in 2016, which resulted in Mr. Shkreli's slate of directors, including Kevin Mulleady and Akeel Mithani, being elected to the Board. But despite plaintiffs' insinuation that Mr. Mulleady and Mr. Mithani were controlled by Mr. Shkreli (*see* Am. Compl. (ECF 87) ¶ 41-42, 48), the record shows otherwise. *See* Shkreli Decl. ¶ 81 (Mr. Mulleady and Mr. Mithani "more often than not . . . ignore, or at least do not follow" Mr. Shkreli's suggestions); Mulleady Dep. Tr., at 122:14-123:10 (stating that Mr. Mulleady has never followed up on "a very strong majority – high majority" of Mr. Shkreli's ideas); Mithani Dep. Tr., at 259:10-18 (stating that "[n]one of [Mr. Shkreli's] ideas were good" and that Mr. Mithani told Mr. Shkreli that). Nor were plaintiffs able to develop any evidence that Mr. Shkreli's lawful exercise of his rights as a shareholder had any effect on the company's decisions relating to Daraprim. Shkreli Decl. ¶ 62-63 ("The proxy fight was totally unrelated to Vyera's sale and distribution of Daraprim.").

Finally, there is also no basis to hold Mr. Shkreli liable on the theory that he "participated" in Vyera's alleged scheme to monopolize the market for Daraprim. In its Motion to Dismiss Order, the Court relies upon the Supreme Court's opinions in *Hartford-Empire Co. v. United States*, 323 U.S. 386 (1945) and *Lorain Journal Co. v. United States*, 342 U.S. 143 (1951), stating: "An individual may be held liable under the Sherman Act to the extent that individual has 'participated in violations of' the antitrust laws, such as by 'negotiating, voting for[,] or executing agreements which constituted steps in the progress of the conspiracy.'" ECF 229, at 35-36. However, neither *Hartford-Empire* nor *Lorain Journal* supports application of a "participation" theory of liability in

a Section 2 monopolization case. And even if those cases do support application of such a theory, Mr. Shkreli cannot be found liable based upon such a theory.

The Supreme Court’s holding in *Hartford-Empire* does not establish grounds to hold Mr. Shkreli liable. The facts in that case are very different from the facts here. *Hartford-Empire* involved an industry-wide conspiracy involving various horizontal exclusionary agreements amongst 12 competing corporations and 101 individuals associated with those corporations as officers and directors to create and maintain a monopoly. *Hartford-Empire*, 323 U.S. at 392. The allegations here are against a single corporate entity and two of its former officers and directors, alleging monopoly maintenance and agreements in restraint of trade, analyzed under the rule of reason. The gravamen of the Amended Complaint, indeed the first count, is single-firm conduct—monopoly maintenance in violation of Section 2 of the Sherman Act by Vyera. Am. Compl. (ECF 87) ¶ 65-66. And while the Amended Complaint alleges that the distribution and supply agreements violated Section 1, plaintiffs do not allege the type of wide-ranging conspiracy that existed in *Hartford-Empire*. We are not aware of any case in the intervening 76 years since *Hartford-Empire* was decided that has adopted a “participation” theory and applied it in the context of a case alleging monopolization under Section 2 and agreements in restraint of trade under Section 1.<sup>7</sup>

In addition, the Supreme Court’s opinion in *Lorain Journal* did not examine, nor was the Court asked to rule on, the grounds on which any individual defendants were found liable. Instead,

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<sup>7</sup> A corporation cannot conspire with its officers, employees or agents to violate the antitrust laws. *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 769 (1984); *Mahmud v. Kaufmann*, 496 F. Supp. 2d 266, 275 (S.D.N.Y. 2007) (Conner, J.) (“It is well-established that the Sherman Antitrust Act does not apply to concerted action among officers or employees of the same enterprise acting as such.”). Thus, Mr. Shkreli cannot be found liable based on any theory that he “conspired” with Vyera. The only “conspiracy” that could conceivably be found is one between Vyera and each of its distribution and supply partners. But this theory fails because the record is devoid of the required “concerted action” by Vyera’s counterparties, either with Vyera or among themselves. See Vyera’s Memorandum of Law, at 43-46; Mulleady’s Memorandum of Law.

the Court merely noted, without critique or analysis, that certain individual defendants were alleged to have “participated in the conduct alleged to constitute the attempt to monopolize.” *Lorain Journal*, 342 U.S. at 145 n.2. These *dicta* do not support the establishment of a rule that individuals may be liable for “participation” in an alleged monopolization scheme.<sup>8</sup>

But even if the *Hartford-Empire* “participation” standard is the correct rule to apply to this case, plaintiffs have failed to show that Mr. Shkreli can be held liable. As explained above in Section I.A.2, the record shows that Mr. Shkreli was not involved in the allegedly anticompetitive agreements, so he cannot be found to have “participated” in them. *See* Shkreli Decl. ¶¶ 43, 57, 60.

#### **IV. PLAINTIFFS’ REQUESTED RELIEF IS BOTH UNAVAILABLE AND OVERBROAD**

##### **A. Mr. Shkreli Cannot Be Held Jointly & Severally Liable With The Company Defendants**

Plaintiffs seek equitable monetary relief in the form of disgorgement from the Defendants, and claim that Mr. Shkreli is jointly and severally liable for such a judgment. However, the Supreme Court’s holding in *Liu v. Sec. & Exch. Comm’n*, \_\_\_ U.S. \_\_\_, 140 S. Ct. 1936, 1945 (2020) forecloses plaintiffs from pursuing disgorgement from Mr. Shkreli on a joint and several liability theory.

In assessing whether joint and several liability may be applied to the equitable remedy of disgorgement, the Supreme Court held that “[w]hile equity courts did not limit profits remedies to particular types of cases, they did circumscribe the award in multiple ways to avoid transforming it into a penalty outside their equitable powers.” *Id.* at 1944. Thus, “[t]he rule against joint-and-several liability for profits that have accrued to another appears throughout equity cases awarding

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<sup>8</sup> Indeed, the Northern District of California noted in *Murphy Tugboat* that “there is no discussion whatever in” either case (*Hartford-Empire* or *Lorain Journal*) “of liability of officers or directors.” 467 F. Supp. at 851 n.6.

profits.” *Id.* at 1945. In other words, allowing joint and several liability “runs against the rule to not impose joint liability in favor of holding defendants liable to account for such profits only as have accrued to themselves . . . .” *Id.* at 1949 (citations omitted).

Still, the Supreme Court held, joint and several liability may be imposed against “partners engaged in concerted wrongdoing.” *Id.* at 1949. However, even that has limitations. First and foremost, the cases cited approvingly by the Court show this exception to the rule to be quite limited. For instance, it does not extend to a corporation’s officers and directors. Specifically, in *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1877), the Supreme Court overturned a joint and several damages award against a company’s employee in a patent infringement case. *Id.* at 140. Although the Court found that the individual employee entered into several of the contracts that led to the alleged infringement, the Court held that the contracts were made on behalf of his employer and the employee received no benefit therefrom. *Id.* He received only his usual salary. *Id.* Thus, it was not proper to impose joint and several liability on the employee for an accounting of the company’s profits.

Taking this, and other precedent, into account, the Supreme Court, in *Liu*, remanded the case before it back to the District Court to consider whether joint and several liability was appropriate under the circumstances of that case. 140 S. Ct. at 1950. Among the factors the Supreme Court instructed the District Court to consider included whether the individual defendants were mere passive recipients of their enterprise’s profits, whether their finances – as husband and wife – were commingled, and whether they personally enjoyed “the fruits of the scheme.” *Id.* at 1949. None of those factors is at play in this case and therefore Mr. Shkreli cannot be subject to joint and several liability for Vyera’s profits, to the extent that any can be shown.

Mr. Shkreli invested approximately \$18 million dollars into Vyera when he founded it. Shkreli Decl. ¶ 15. Since that date, he has not taken a salary or received any other form of compensation from Vyera or Phoenixus. *Id.* ¶ 17. And while Mr. Shkreli owns shares in Phoenixus, plaintiffs have not offered any evidence to show the extent of any “ill-gotten gains” that Mr. Shkreli enjoyed as a result of the alleged scheme. In fact, plaintiffs’ expert on monetary relief, Scott Hemphill, expressly stated that he was offering no opinion on the amount of the individual defendants’ monetary gain. Hemphill Dep. Tr., at 247:10-249:3. In short, plaintiffs have failed to meet their burden that Mr. Shkreli has enjoyed any of “the fruits of the scheme” alleged in this case, and thus, under *Liu*, he cannot be held jointly and severally liable for Vyera’s profits.

**B. Any Injunctive Relief Ordered Against Mr. Shkreli Must Be Narrowly Tailored; It May Not Unduly Harm Or Penalize Him**

Under the FTC Act, the FTC may “in proper cases[,]” seek a permanent injunction. 15 U.S.C. § 53(b). Such relief is forward looking. *United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953). Its “purpose . . . is to prevent future violations.” *Id.* Thus, injunctive relief is not punitive. To be entitled to injunctive relief, plaintiffs must show that a permanent injunction is necessary—*i.e.*, because harm to competition is ongoing or is likely to recur, an injunction is needed to stop it. *See id.* (a permanent injunction is appropriate where the moving party shows that “there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive”); *see also FTC v. Abbvie Inc.*, 976 F.3d 327, 380 (3d Cir. 2020) (a plaintiff seeking an injunction must prove a “cognizable danger” of a recurrent violation; proof that a recurrent violation is “merely possible” is insufficient); *FTC v. Evans Prods. Co.*, 775 F.2d 1084, 1087 (9th Cir. 1985) (“As a general rule, [p]ast wrongs are not enough for the grant of an injunction; an injunction will issue only if the wrongs are ongoing or likely to recur.”);

*Federal Trade Comm’n v. Facebook, Inc.*, No. 20-3590, 2021 WL 2643627, at \*18 (D.D.C. June 28, 2021) (declining to award the FTC injunctive relief where the only actionable conduct occurred years prior to the filing of the complaint and where “no actionable violation is either ongoing or about to occur”).

There is no factual foundation on which the Court could base a permanent injunction, because the record shows that as of the time the Complaint was filed, Mr. Shkreli was not “violating” or “about to violate” the law. The Amended Complaint makes reference to communications Mr. Shkreli had—months before the Complaint was filed—with Vyera executives about the company, and contains a vague allegation that Mr. Shkreli was “looking for” drugs other than Daraprim to carry out a similar scheme (Am. Compl. (ECF 87) ¶ 293), but no such evidence was developed in discovery. Moreover, even if there had been ongoing anticompetitive conduct at the time the Complaint was filed, since that time three more generic companies have had their ANDAs for generic Daraprim approved, so there is no risk of any harm to competition by any acts of Vyera or the individual defendants. Thus there is simply no evidentiary support for any ongoing or imminent violations of the law, and thus no basis for any type of injunction.

But even if there were such a basis for an injunction against Mr. Shkreli, the challenged conduct in this case—even though proper—has no likelihood of continuing into the future. Shkreli Decl. ¶ 83. Indeed, Mr. Shkreli recognizes that, after he is released from prison, his “employment opportunities going forward are [going to be] fairly limited.” *Id.* at 82; Shkreli Dep. Tr., at 353:6-23. He testified that he is not interested in acquiring commercial assets and being involved in the “day-to-day affairs of commercializing medicine.” *Id.* at 354:7-355:17; Shkreli Decl. ¶ 83. Instead, he would like to pursue experimental and research-based opportunities related to

discovery of new medicines and new uses for existing medicines, similar to the work that he did prior to Vyera’s acquisition of Daraprim. Shkreli Dep. Tr., at at 354-355:358:8; Shkreli Decl. ¶ 83. None of that would involve him in pricing pharmaceuticals, sourcing API, or contracting with pharmaceutical distributors. And, thus, an injunction is unnecessary as against him.

If the Court were to disagree, and find some injunctive relief appropriate in this case, the relief plaintiffs seek is grossly overbroad. An injunction must not go any further than necessary to prevent future violations. As such, “the injunction must not ‘unduly harm the defendants . . . [by] put[ing] them out of business, but [must] simply ensure that they will conduct their business in a manner which does not violate Section 5 of the FTC Act.’” *F.T.C. v. Ross*, 897 F. Supp. 2d 369, 387 (D. Md. 2012) (quoting *F.T.C. v. Kitco of Nev., Inc.*, 612 F. Supp. 1282, 1296 (D. Minn. 1985)), *aff’d*, 743 F.3d 886 (4th Cir. 2014). In other words, the court must ensure— as required in all cases, under Federal Rule of Civil Procedure 65—that any injunctive relief is “narrowly tailored to fit specific legal violations’ and avoid[s] unnecessary burdens on lawful commercial activity.” *Syntel Sterling Best Shores Mauritius Ltd. v. Trizetto Grp., Inc.*, 15 Civ. 211, 2021 WL 1553926, at \*14 (S.D.N.Y. Apr. 20, 2021) (Schofield, J.) (quotation and citation omitted).

Plaintiffs do not precisely define the injunctive relief they seek in this case. However, they do seek to penalize Mr. Shkreli by enjoining him from owing in part or whole or working for a company engaged in the pharmaceutical industry.<sup>9</sup> As the District of Maryland held in *F.T.C. v. Ross*, seeking such broad relief is improper.

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<sup>9</sup> Plaintiffs’ use of the vague and undefined term “pharmaceutical industry” is enough by itself to deny the relief sought. The Second Circuit has vacated, and affirmed the denial of, injunctions that are impermissibly vague. *See Metro. Opera Ass’n v. Local 100, Hotel Emps. & Rest. Emps. Int’l Union*, 239 F.3d 172, 178 (2d Cir. 2001) (“the vagueness of this injunction serves as sufficient reason to require that we vacate it”); *Sanders v. Air Line Pilots Ass’n, Int’l*, 473 F.2d 244, 249 (2d Cir. 1972) (affirming denial of injunction because of “the breadth and vagueness of [the injunctive relief] sought”). The relief requested could be interpreted to reach lawful conduct that is totally outside the bounds of the alleged conduct, such as owning stock in a pharmacy company like Walgreens or CVS or publishing an industry journal. Equally vague are plaintiffs’ requests to enjoin defendants’ undefined “course of conduct” and from “engaging in similar and related conduct in the future.” Am. Compl. (ECF 87), at 76 ¶¶ 13-14. Plaintiffs do not define



In that case, the FTC filed suit, seeking injunctive relief, against a group of corporate entities and an individual for alleged deceptive conduct in connection with the sale of computer software. *Ross*, 897 F. Supp. 2d at 374. The relief granted was an injunction restraining the individual defendant from “the marketing and sale of computer security software and software that interferes with consumers’ computer use as well as from engaging in any form of deceptive marketing.” *Id.* at 387. Notably, the Court did not enjoin the individual defendant from working in her chosen field of marketing and selling computer security software. As the court held, “[s]he may still utilize her marketing talents as long as they are used for legitimate products and ventures and do not contribute to deceiving the public.” *Id.* Thus, to the extent any injunctive relief is entered in this case—which it should not be—such relief should be narrowly tailored and not so broad as to bar Mr. Shkreli from working in his chosen field of work. Such an injunction would simply constitute undue punishment, which is not the proper function of an equity court, particularly in a rule of reason antitrust case.<sup>10</sup>

## V. CONCLUSION.

Martin Shkreli respectfully requests that the Court find him not liable and enter judgment in his favor and against Plaintiffs on all Counts asserted against him.

Respectfully submitted,

By: /s/ Christopher H. Casey  
 Christopher H. Casey, Esq. (admitted *pro hac vice*)  
 Jeffrey S. Pollack, Esq. (admitted *pro hac vice*)

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the conduct at issue, nor do they state whether it may have other pro-competitive purposes. As the Eighth Circuit held in *Yamaha Motor Co. v. Fed. Trade Com.*, 657 F.2d 971, 984 (8th Cir. 1981) an injunction that makes otherwise lawful conduct a *per se* unlawful restraint “goes beyond any reasonable relationship to the [challenged conduct].” *See also Syntel Sterling Best Shores Mauritius Ltd. v. Trizetto Grp., Inc.*, 15 Civ. 211, 2021 WL 1553926, at \*14 (S.D.N.Y. Apr. 20, 2021) (Schofield, J.) (Rule 65 “requires that a permanent injunction be specific and ‘describe in reasonable detail’ what is restrained.” (quoting Fed. R. Civ. P. 65(d))).

<sup>10</sup> The State Plaintiffs’ claims for injunctive relief should be rejected as well, for all the reasons in Mulleady’s Pre-Trial Memorandum. *See* Mulleady Pre-Trial Memorandum of Law.

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**CERTIFICATE OF SERVICE**

I certify that on October 20, 2021, a copy of the foregoing Defendant Martin Shkreli's Pretrial Memorandum of Law was served upon all counsel of record in matter by email.

/s/ Andrew J. Rudowitz  
Andrew J. Rudowitz